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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,359	09/10/2004	Johan Bernard Ubbink	3714652.00504	5698
29157	7590	11/24/2010		
K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER BADR, HAMID R	
			ART UNIT 1781	PAPER NUMBER
			NOTIFICATION DATE 11/24/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

### Office Action Summary

**Application No.**

10/507,359

**Applicant(s)**

UBBINK ET AL.

**Examiner**

HAMID R. BADR

**Art Unit**

1781

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-11,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-11,13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicants' amendment filed 9/20/2010 is acknowledged.
  2. Rejection of claims 11-12 under 35 U.S.C. 112 first paragraph (description) is withdrawn per applicants' amendment.
  3. Rejection of claims 1, 3, and 5-14 under 35 U.S.C. 112 second paragraph is withdrawn per applicants amendment.
- Claims 1, 3, 5-11 and 13-14 are being considered on the merits.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 5-11, and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casas-Perez (US 5,480,641; hereinafter R1) in view of Cavadini et al. (US 5,968,569; hereinafter R2), Klapwijk et al. (EP 0 298 605; hereinafter R3) and Van Lengerich (US6,500,463; hereinafter R4).
3. R1 discloses methods and product for direct feed microorganisms such as *Lactobacillus reuteri* delivered in pellets (compacted whey particles) (Abstract).
4. R1 teaches coating the palletized whey particles with lyophilized *L. reuteri* cells suspended in oil (col. 3, lines 55-57) or the suspension of *L. reuteri* in oil is mixed with whey powder and then the mixture is compressed into pellets (compressed whey

particles) or tablets. (Col. 3, lines 62-65). Given that oil is impermeable to moisture, the pellet will be impermeable to moisture.

5. It is noted that whey inherently contains lactose in the range of 50-70%, thus it is clear that an inert carbohydrate is included in the pellets as taught by R1 and as presently claimed. It is also noted that whey contains proteins.

6. The pellets may have different sizes (Col.4, lines 10-20) for instance particles which go through mesh 8 (2.38 mm) but retained by mesh 20 (0.84 mm) or particles going through mesh 0.25 inch (6.35 mm) but retained by mesh 8 (2.38 mm). It is clear that pellets having size between 2.38 mm and 0.25 inch would inherently possess volume as presently claimed.

7. R1 teaches that whey pellets may contain  $5 \times 10^7$  to about  $10^8$  cells/g whey (Col. 4, lines 25-27).

8. Given that the cells are lyophilized (below water activity of 0.3) and the suspending agent and binder is oil and the supporting matrix is whey powder, the water activity of less than 0.3 will be inherent to the pellets.

9. R1 teaches using 1—15 lbs/sq. in pressure to produce the compacted pellets (Col. 4, lines 10-11)

10. R1 is silent regarding the water activity ( $A_w$ ) of the pellets, an additional coating on the pellets, and incorporation of encapsulated microorganism in the pellets.

11. R2 discloses food or feed pellets containing probiotic microorganisms. R2 discloses that in order to increase the probability of survival of microorganisms, the probiotics may be encapsulated for instance in sugar matrix, fat matrix or

polysaccharide matrix. Therefore, it would have been obvious to incorporate encapsulated organisms in the pellets produced by the method of R1.

12. R2 is silent regarding the water activity of the product. R2 is also silent regarding the amount of coating on the product.

13. R3 discloses the process of making supported lactic acid bacterial compositions where the water activity of the supported flora products is 0.3 or less, particularly 0.2 or less (page 4 line 8). Since the critical role of the water activity of a product on the survival of lactic acid bacteria (probiotics) is disclosed by R3, it would be obvious to adjust the water activity of the product either by employing materials with water activity below 0.3 (as disclosed by R1) or drying the product to a water activity below 0.3 as disclosed by R3.

14. While R1 teaches of coating the compacted pellets with oil, R1, R2 and R3 are generally silent regarding additional coating of pellets and the amount of coating as presently claimed.

15. R4 discloses that the coatings for pelletized products containing sensitive materials including microorganisms, enzymes or chemicals play the role of protecting agents against environmental elements such as oxygen, moisture, light etc. as well as being the controlled release agents. R4 teaches of increasing the thickness of the coating on the extrudate or pellet delays release of the encapsulant. Further, R4 discloses that the amount of coating may vary from 0.5% to 50% by weight based on the weight of the total product. (col. 19, line 20 to col. 20 line 3).

16. Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over R1-R4 as applied above, further in view of Van Lengerich (WO 99/48372; hereinafter R5).

17. R5 teaches of the use of the pellets as food or their incorporation into foods, nutraceuticals and pharmaceuticals . A variety of foods having various moisture levels are mentioned. The product comprises at least one component of the food e.g. yogurt which can contain nonfat dry milk, or gelatin, or lactose (Page 33 line 14 to page 34 line 16).

18. R5 teaches of the incorporation of pellets containing live micro-organisms into various foods where the food and the pelleted product share at least one ingredient. R5 mentions that the encapsulated product may be incorporated, with or without grinding, into foods for human or animal consumption. The foods, which are exemplified do share, at least, one component with the granulated product (Page 33, lines 14-23 and page 34, lines 1-2).

19. Therefore, it would have been obvious to one of ordinary skill in the art , at the time the invention was made, to modify the teachings of R1 by incorporating encapsulated probiotics as disclosed by R2 and lowering the water activity of the pellets as taught by R3 and coating the pellets as taught by R4 to make the probiotic delivery system as instantly claimed. One would have done so to receive the benefits of a product which could be used as a delivery system for dried viable organisms which could be used in various food and feed applications as taught by R5. Absent any evidence to contrary and based on the combined teachings of the cited references,

there would have been a reasonable expectation of success in making a probiotic delivery system with characteristics as presently claimed.

### ***Response to Arguments***

Applicants' arguments have been reviewed thoroughly. These arguments do not deem persuasive for the following reasons:

1. Applicants argue that R1 does not teach the incorporation of encapsulated organisms into the pellets.
  - a. The incorporation of encapsulated organisms in the pellets is a new amendment which is now addressed by Cavadini et al. (R2). Therefore, the argument is moot.
2. Applicants argue that the inner matrix of their invention comprises 40-70% carbohydrate.
  - a. Whey powder utilized in making the pellets of R1, contains the claimed range of lactose.
3. Applicants argue that the amount of coating in the claimed pellets is 8-18%.
  - a. Van Lengrich (R4) discloses a coating range of 0.5-50% of the total weight of the product. This range includes the presently claimed range.
4. Applicants argue that certain limitations for instance additional coating of pellets is not disclosed by R1 or R2 misses the teachings of R1.
  - a. It should be realized that the rejection is an obviousness type rejection so that all limitations of the independent claims are not required to be disclosed by all involved

references. For instance in the current rejections, R2 teaches of encapsulating the microorganisms for an improved survival rate. Therefore, R2 is teaching of a solution to a problem with which the applicants were concerned.

5. Applicants argue that Klapwijk is entirely directed to bread making and sourdough fermentation.

a. Klapwijk teaches of a fundamental idea which has been presently claimed. The idea that the product containing probiotics should have a water activity of less than 0.3 is clearly taught by Klapwijk. Therefore, Klapwijk is a pertinent teaching reference. Since the references teach or suggest all the features of the claimed invention, the examiner does regard any steps in the claimed invention to be inventive steps.

### ***Conclusion***

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R. Badr  
Examiner  
Art Unit 1781

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1781